July 29, 2020

Julianne Cappell
Quality Management Coordinator
Department of Laboratory Medicine and Pathology
Mayo Clinic
200 1st St NW
Rochester, MN 55905

Re: EUA200155/A001
Trade/Device Name: SARS-CoV-2 Molecular Detection Assay
Dated: June 30, 2020
Received: June 30, 2020

Dear Ms. Cappell:

This is to notify you that your request to update the Instructions for Use (IFU) of the SARS-CoV-2 Molecular Detection Assay to; (1) validate two additional extraction instruments for isolation and purification of RNA from the respiratory specimens, and (2) remove the ORF1ab target from the authorized assay, is granted. Upon review, we concur that the data and information submitted in EUA200155/A001 supports the requested updates for use with the SARS-CoV-2 Molecular Detection Assay. By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the SARS-CoV-2 Molecular Detection Assay issued on April 20, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health